REMARKS

In the Office Action, Claims 1 and 6-11 were objected to under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, has possession of the claimed invention. Claims 1 and 6-11, and 22-27 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is mostly nearly connected, to make and/or use the invention. Claims 1 and 6-11, and 22-27 were objected to under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention. Claims 8-11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 1, 8, 10, 22, 25 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Falconer et al., as evidenced by the teachings of Kartinos *et al.* and Mullins. Claims 1, 6, 8, 10, 22, 25 and 27 are rejected under 35 U.S.C. § 102(b) as being anticipated by Martyn *et al.* as evidenced by the teachings of Kartinos *et al.* and Mullins. Claims 1, 8-11, 22, 25 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Falconer *et al.* in view of Love. Claims 1, 6, 8-11, 22 and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Martyn *et al.* in view of Love.

Claims 1, 6-11 and 22-27 are now pending in the application. Claims 1, 6-11 and 22-27 have been rejected. Claims 1, 8, 9 and 10 have been amended. Reexamination and reconsideration of the claims are respectfully requested.

Rejection of Claims 1 and 6-11 Under 35 U.S.C. §112, First Paragraph Should be Withdrawn

Claims 1 and 6-11 were rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, has possession of the claimed invention. Claim 1 has been amended. Therefore, it is submitted that

amended claims 1 and 6-11 overcome the outstanding rejection and do not raise any new issues. Withdrawal of the rejection is requested.

Claims 1 and 6-11, and 22-27 were rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is mostly nearly connected, to make and/or use the invention.

Claims 1 and 6-11 and 22-27 were rejected because, as the examiner states "Applicant fails to adequately describe as to what Applicant defines or considers as a 'nonabsorbable' biocompatible solution'. For example, nowhere in the present specification does Applicant render a definition of the term "nonabsorbable biocompatible solution" or cite an example of the term thereof". This rejection is respectfully traversed for the reasons described below.

Applicant submits that there is sufficient written description for "nonabsorbable biocompatible solution" to enable one skilled in the art to which it pertains to make and/or use the invention, as required by section 112, first paragraph (see M.P.E.P. 2163.02).

"Written description may be satisfied through disclosure of relevant identifying characteristics, *i.e.*, structure, other physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation function and structure, or some combination of such characteristics." *Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. §112, First Paragraph, Written Description Requirement.* Moreover, "[a] specification may, within the meaning of 35 U.S.C. § 112, first paragraph, contain a written description of a broadly written claimed invention without describing all species that claim encompasses." *Utter v. Jiraga*, 845 F.2d 993, 6 USPQ2d 1709 (Fed. Cir. 1988).

Applicant respectfully submits that functional features are implicit in the term "nonabsorbable biocompatible solution" as used to further define an agent that increases retrievable ductal fluid from a breast duct.

Thus, applicant submits that the term "nonabsorbable biocompatible solution" is clear and definite based on the plain meaning of the term, and respectfully requests reconsideration and withdrawal of the present rejection.

Rejection of Claims 1, 6-11 and 22-27 Under 35 U.S.C. §112, Second Paragraph Should be Withdrawn

Claims 1 and 6-11, and 22-27 were objected to under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention.

Claim 1 was rejected because, as the examiner states "The metes and bounds of Claim 1 are rendered uncertain by the term 'nonabsorbable compatible[sic] solution' because it is unclear as to the subject matter Applicant intends to direct the subject matter of the claimed invention."

Applicant respectfully traverse the foregoing rejection on the grounds that the term "nonabsorbable biocompatible solution" is clear and definite, in view of the teachings in Applicants' specification and the knowledge available in the art at the time of the invention. As mentioned previously, the term "nonabsorbable biocompatible solution" is axiomatic. Applicant respectfully submit that functional features are implicit in the term "nonabsorbable biocompatible solution" as used to further define an agent that increases retrievable ductal fluid from a breast duct.

In view of the foregoing, it is Applicants' position that the term "nonabsorbable biocompatible solution" as used in the pending claims is clear and definite and respectfully requests reconsideration and withdrawal of the present rejection.

Claim 7 was rejected because the examiner suggests that "Claim 7 is rendered vague and indefinite by the phrase 'wherein the agent comprises a carbonated fluid comprising super oxygenated fluid that is colder than room temperature before administration' because it is unclear as to the subject Applicant intends to direct the invention". Applicant respectfully traverse the foregoing rejection on the grounds that Claim 7 is a proper dependent claim, the subject matter of which further defines the members of the recited Markush group of Claim 1. The examiner states that "For instance, it appears that the claimed limitations are outside the scope of the recited Markush group of Claim 1, since it is uncertain as to whether any, if any, of the agents that increase retrievable secreted ductal fluid from a breast duct 'comprises a carbonated fluid comprising super oxygenated fluid that is colder than room temperature before administration'".

Applicant disagrees. The claimed limitations of Claim 7 are not "outside the scope of the recited Markush group". Claim 7 properly and clearly defines a functional characteristic of a solution that may be applicable to a number of the members recited in the Markush group of Claim 1. Whether or not the examiner believes that any the agents described in the Markush group of Claim 1 has this limitation is irrelevant. Claim 7 is not vague and indefinite, but is clear and defined. Therefore, Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claim Objections

Claims 8-11 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The examiner states that: "Claims 8-11 fail to further the subject matter of independent Claim 1, that is, a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient because the claimed invention is a one-step process comprising the intraductal administration to a patient an agent an agent that increases retrievable secreted ductal fluid from a breast because the claimed process steps of Claims 8-11 are directed to post-processing steps not required by Claim 1". This rejection is respectfully traversed for the reasons described below.

Claims 8-11 positively recite the additional step or steps of collecting or analyzing ductal fluid. Claim 1 does not positively recite these specific steps. Thus, by definition, claims 8-11 limit the scope of Claim 1 by requiring the additional steps of collecting or analyzing the ductal fluid sample obtained through the method described in Claim 1. Applicant respectfully requests reconsideration and withdrawal of the present objection.

Rejection of Claims 1, 8, 10, 22, 25 and 27 Under 35 U.S.C. §102(b) Should be Withdrawn

Claims 1, 8, 10, 22, 25 and 27 were rejected to under 35 U.S.C. § 102(b) as being anticipated by Falconer *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos et al., and U.S. Patent No. 6,235,305 to Mullins. Claim 1 was rejected because, as the examiner states "...Falconer *et al* teaches a method for preparing for intraductal retrieval of fluid,

cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin (a growth hormone), ouabain or both dissolved in a solution of [Na+], [K+] and [Cl-] containing Dextran Blue 2000 (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins)." Applicant respectfully traverse.

Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution. The examiner argues that Falconer *et al* anticipates Claim 1 because it discloses a nonabsorbable biocompatible compound (Dextran Blue 2000) that is used increase water content of wet tissue in treated mammary gland tissue. Applicant disagrees. Falconer *et al.* describes an in vivo experiment in rabbits to measure the effect of prolactin and ouabain on mammary alveolar tissue. Falconer *et al.* does not teach a method of using a nonabsorbable biocompatible solution (Dextran Blue 2000) as an agent to increase retrievable ductal fluid from a breast duct. In fact, as evidenced on page 182, Column 2, lines 13-15, Falconer *et al.* explicitly states that Dextran Blue 2000 is used to "...locate the injected glands at the time of removal". Similarly, Falconer *et al.* does not teach a method for administering intraductally to a patient an agent that increases retrievable ductal fluid from a breast duct. As evidenced on page 185, Column 1, lines 4-8, Falconer *et al.* explicitly states that "From these results we conclude that *in vitro* and *in vivo* prolactin has significant influence upon Na+ and K+ content (and therefore Na+/K+ ratio) of mammary alveolar tissue". Alveolar tissue is comprised of glandular tissue and secreting cells that surround the ductal system (see page 182, Column 2, lines 29-33). Therefore, Falconer *et al.* does not disclose that prolactin and ouabain increases water content in breast ducts, but instead, discloses an increase in water content of the surrounding alveolar tissue. There is no teaching or suggestion in Falconer *et al.* of an agent that increases retrievable ductal fluid from a breast duct.

Therefore, because Falconer *et al.* does not anticipate neither Claim 1 nor dependent Claims 8, 10, 22, 25 and 27 for all of the reasons stated above, the rejection should be withdrawn.

Claims 1, 6, 8, 10, 22, 25 and 27 were rejected to under 35 U.S.C. § 102(b) as being anticipated by Martyn *et al.* as evidenced by the teachings of U.S. Patent No. 4,339,433 to Kartinos et al., and U.S. Patent No. 6,235,305 to Mullins. Claim 1 was rejected because, as the examiner states "Martyn teaches a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient comprising administering intraductally to the patient prolactin as either an emulsion or an aqueous solution, made by dissolving prolactin in NaOH and diluting with phosphate buffered saline containing Blue Dextran (a nonabsorbable biocompatible solution, as evidenced by the teachings of Kartinos and Mullins)." Applicant respectfully traverse.

As mentioned previously, Claim 1, as amended, recites a method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising administering intraductally to the patient an agent that increases retrievable ductal fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Martyn *et al.* describes an *in vivo* experiment in rabbits to measure the effect of prolactin and progesterone on lipogenic-enzyme activity and glycerolipid synthesis. Martyn *et al.* does not teach a method of using a nonabsorbable biocompatible solution (Blue Dextran 2,000,000) as an agent to increase retrievable ductal fluid from a breast duct. In fact, as evidenced on page 326, Column 1, lines 28-41, as well as Table 4 on page 326, Blue Dextran mixed with Phosphate-buffered saline had no effect on fatty acid synthesis. Similarly, there is no teaching or suggestion that any agent described in Martyn *et al.*, including Blue Dextran, would increase retrievable fluid from a breast duct.

Therefore, because Martyn *et al.* does not anticipate neither Claim 1 nor dependent Claims 6, 8, 10, 22, 25 and 27, the rejection should be withdrawn.

The Rejections Under 35 U.S.C. §103(a) Should be Withdrawn

Claims 1, 8-11, 22, 25 and 27 are rejected under 35 U.S.C. 103 as being unpatentable over Falconer *et al.*, *supra* in view of U.S. Patent No. 6,221,622 to Love. Applicants traverse this rejection. Applicants submit that Falconer *et al.* neither anticipates the claims nor are they made obvious by Love. Because Falconer *et al.* does not teach a method of using a

nonabsorbable biocompatible solution as an agent to increase retrievable fluid from a breast duct, it cannot anticipate all the elements of the claimed invention. Love teaches the intraductal administration of physiological saline to a breast duct for retrieval of fluid. Love does not disclose an agent to increase retrievable fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Because Love does not recite any agent that increases the amount of retrievable fluid in a breast duct, it cannot anticipate all the elements of the claimed invention. Combining Falconer *et al.* with the Love cannot make up for the deficiencies of Falconer *et al.* with respect to the claimed invention. Neither Falconer *et al.* nor Love teach a method of using a nonabsorbable biocompatible solution as an agent to increase retrievable fluid from a breast duct, nor can they be combined to anticipate all the elements of the claimed invention. *Prima facie* obviousness has not been established under such conditions. The Applicants respectfully requests that the rejection be withdrawn.

Claims 1, 8-11, 22, 25 and 27 are rejected under 35 U.S.C. 103 as being unpatentable over Martyn *et al. supra* in view of U.S. Patent No. 6,221,622 to Love. Applicants traverse this rejection. Applicants submit that Martyn *et al.* neither anticipates the claims nor are they made obvious by Love. Because Martyn *et al.* does not teach a method of using a nonabsorbable biocompatible solution as an agent to increase retrievable fluid from a breast duct, it cannot anticipate all the elements of the claimed invention. Love teaches the intraductal administration of physiological saline to a breast duct for retrieval of fluid. Love does not disclose an agent to increase retrievable fluid from a breast duct, wherein the agent is a nonabsorbable biocompatible solution. Because Love does not recite any agent that increases the amount of retrievable fluid in a breast duct, it cannot anticipate all the elements of the claimed invention. Combining Martyn *et al.* with the Love cannot make up for the deficiencies of Martyn *et al.* with respect to the claimed invention. Neither Martyn *et al.* nor Love teach a method of using a nonabsorbable biocompatible solution as an agent to increase retrievable fluid from a breast duct, nor can they be combined to anticipate all the elements of the claimed invention. *Prima facie* obviousness has not been established under such conditions. The Applicants respectfully requests that the rejection be withdrawn.

Rejection of Claims for Obviousness-Type Double Patenting

Claims 1, 6-11 and 22-27 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 157-165 of co-pending Application No. 09/907,581. Applicant will continue to defer consideration of filing a terminal disclaimer until determination of allowable subject matter by the Patent Office.

CONCLUSION

In light of the amendments and arguments presented above, Applicants respectfully submit that the claims are in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 502855 referencing attorney docket number 12.023011.

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Marked-up Version of Amendment

Please amend claims 1, 8, 9 and 10 as follows:

1. (Currently amended) A method for preparing for intraductal retrieval of fluid, cells and/or other material from a breast duct of a patient, comprising:

administering intraductally to the patient an agent that increases retrievable [secreted] ductal fluid from a breast duct, wherein the agent is selected from the group consisting of a hypotonic solution, a buffered solution, a nonabsorbable biocompatible solution, a protein, a colloid, a sugar, a polymer, mannitol, sorbitol, glucose, glycerol, sucrose, raffinose, fructose, lactulose, polyethyleneglycol (PEG), maltodextrin, dextran, dextran 70, hydroxyethyl starch, fluid gelatin, a synthetic colloid, an antibody, a binding protein, albumin, a hormone, a natural herb, an extract from a natural herb, silymarin, a surfactant, a growth factor, oxytocin, prolactin, an organic molecule, a muscle relaxant, and a ductal orifice dilator.

8. (Currently amended) A method as in claim 1, further comprising collecting a portion of the increased retrievable [secreted] ductal fluid from the breast duct.

9. (Currently amended) A method as in claim 8, wherein collecting comprises accessing a breast duct with a device and withdrawing a portion of the increased retrievable [secreted] ductal fluid into the device.

10. (Currently amended) A method as in claim 8, further comprising the step of analyzing one or more of cells, fluid or other material [in] from the breast duct after the retrievable [secreted] ductal fluid has been increased and a portion of it has been collected.